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UNCLAS SECTION 01 OF 03 OTTAWA 001383

SIPDIS

STATE FOR WHA/CAN PNORMAN AND EB/DCT
USDOC FOR ITA GWARD AND CBUSQUETS
DEPT PASS USTR SCHANDLER
DEPT ALSO PASS FDA DAUTOR AND MECKLES

E.O. 12958: N/A

TAGS: ECON ETRD EIND CA

SUBJECT: INTERNET PHARMACIES: MANITOBA LEADS THE WAY IN EXPORTS TO THE U.S.

REFTEL: 2002 OTTAWA 2048

¶11. SUMMARY - WITH STRONG SUPPORT FROM THE PROVINCIAL GOVERNMENT AND REGULATOR, MANITOBA HAS BECOME A HUB FOR THE GROWING CROSS-BORDER TRADE IN PHARMACEUTICALS FROM CANADA TO THE U.S. CANADIAN INTERNET PHARMACIES, SOME OF WHICH FILL MORE THAN 1000 PRESCRIPTIONS A DAY, HAVE BEEN SUCCESSFUL IN TAKING ADVANTAGE OF THE DISPARATE U.S. AND CANADIAN MARKET PRICES FOR PHARMACEUTICALS AND LEGAL UNCERTAINTIES ON BOTH SIDES OF THE BORDER. MANITOBA'S STRONG PROMOTION OF THE INDUSTRY IS IN STARK CONTRAST WITH THE CAUTIOUS APPROACH TAKEN BY OTHER PROVINCES, ESPECIALLY ONTARIO. THE FUTURE OF THE INDUSTRY WILL DEPEND ON THE INTERNET PHARMACIES' ABILITY TO RESPOND TO THE INCREASING PRESSURE ON THE SUPPLY OF PHARMACEUTICALS AND NAVIGATE THE MURKY LEGAL AND ETHICAL WATERS SURROUNDING THE TRADE. END SUMMARY.

--PHARMACEUTICAL EXPORTS - A BOON FOR MANITOBA--

¶12. MANITOBA HAS BECOME A MAJOR HUB IN A GROWING TRADE IN PRESCRIPTION PHARMACEUTICALS FROM CANADA TO THE U.S., MUCH OF WHICH IS NOW ORDERED OVER THE INTERNET AND FULFILLED BY MAIL. MANITOBA-BASED INTERNET PHARMACIES ACCOUNT FOR WELL OVER HALF OF THE ESTIMATED USD 500 MILLION WORTH OF PRESCRIPTION DRUGS SOLD TO THE U.S. FROM CANADA LAST YEAR. THE MANITOBA PHARMACEUTICAL ASSOCIATION (MPA), WHICH REGULATES PHARMACIES IN THE PROVINCE, ESTIMATES THAT 53 MANITOBA PHARMACIES ARE INVOLVED IN CROSS-BORDER TRADE WITH THE UNITED STATES. THE INDUSTRY HAS CREATED UPWARDS OF 2000 JOBS IN TOWNS THROUGHOUT THIS TRADITIONAL MANUFACTURING AND FARMING PROVINCE.

¶13. KRIS THORKELSON, CHAIRMAN AND CEO OF CANADA DRUGS, ONE OF THE LARGEST INTERNET PHARMACIES IN MANITOBA, INVITED MISSION PERSONNEL FOR A TOUR OF THE COMPANY'S FACILITIES TO HELP DEMONSTRATE THAT THE NEW INTERNET PHARMACIES ARE NOT "FLY BY NIGHT" OPERATIONS, AND THAT THEY HAVE INVESTED HEAVILY IN BRICKS AND MORTAR, AS WELL AS SOPHISTICATED COMPUTER AND ELECTRONIC TRACKING SYSTEMS. CANADA DRUGS FILLS OVER 1000 PRESCRIPTIONS A DAY, ALL FOR EXPORT TO THE UNITED STATES. CUSTOMERS INITIATE AN ORDER BY FAXING OR MAILING TO CANADA DRUGS A COPY OF THEIR U.S. PRESCRIPTION, TOGETHER WITH A POWER OF ATTORNEY FORM THAT WAIVES THE CANADIAN PHARMACIST OF LIABILITY, AND A PATIENT QUESTIONNAIRE. AN IN-HOUSE PHARMACIST AT CANADA DRUGS REVIEWS MATERIALS, A CANADIAN PHYSICIAN CO-SIGNS THE PRESCRIPTION, AND THE PHARMACIST REVIEWS IT A SECOND TIME AFTER A TECHNICIAN FILLS THE ORDER, AND ONCE MORE BEFORE IT IS SHIPPED OUT. EACH ORDER IS CONFIRMED BY PHONE WITH THE CUSTOMER BEFORE IT IS SENT. CANADA DRUGS HAS 18 PHARMACISTS ON STAFF, OVER 40 PHARMACEUTICAL TECHNICIANS, AND APPROXIMATELY 170 STAFF IN TOTAL.

--PROVINCE STEPPING IN TO SUPPORT THE INDUSTRY--

¶14. THE GOVERNMENT OF MANITOBA (GOM) IS A STRONG SUPPORTER OF THE PHARMACEUTICAL EXPORT INDUSTRY AND VIEWS THE NEW BUSINESSES AS A KEY COMPONENT OF ITS PROVINCIAL GROWTH STRATEGY. EXPORTS FROM CANADA STILL ONLY ACCOUNT FOR LESS THAN ONE-HALF OF ONE PERCENT OF THE U.S. PRESCRIPTION DRUG MARKET. THE GOM IS WORKING WITH THE MPA AND THE MANITOBA COLLEGE OF PHYSICIANS AND SURGEONS (MCPS) ON SMOOTHING OUT THE REGULATORY PROCESS TO LEGITIMIZE THE INDUSTRY. AS FAR AS THE GOM IS CONCERNED, EXPORTING PHARMACEUTICALS TO THE U.S. IS NOT ILLEGAL UNDER CANADIAN LAW, AND THEY ARE NOT INTERESTED IN ENFORCING U.S. PROHIBITIONS ON PHARMACEUTICAL PRODUCTS IF THE FDA WILL NOT ENFORCE THEM. THE GOM IS INSTEAD FOCUSED ON ENSURING THAT THE PRACTICE IS SAFE, MEETS CANADIAN FEDERAL AND PROVINCIAL GUIDELINES AND PRACTICES, AND THAT INTERNET PHARMACIES PROVIDE U.S. CONSUMERS WITH THE SAME SAFEGUARDS AND LEVEL OF SERVICE AS CANADIAN CITIZENS.

¶15. ONE OF THE BIGGEST CONCERNS FOR THE PROVINCIAL REGULATORY AUTHORITIES ACROSS CANADA HAS BEEN THE PRACTICE OF CANADIAN PHYSICIANS CO-SIGNING, OR RE-WRITING

PREScriptions FOR U.S. PATIENTS THEY HAVE NEVER SEEN. REGULATORS HAVE QUESTIONED WHETHER SIGNING OFF ON PRESCRIPTIONS WITHOUT PERFORMING AN APPROPRIATE PHYSICAL EXAMINATION IS TANTAMOUNT TO PROFESSIONAL MISCONDUCT. THE MPA HAS WORKED WITH THE MCPS TO CLAMP DOWN ON THE MOST EGREGIOUS CASES WHERE PHYSICIANS WERE "RUBBER STAMPING" MORE THAN 1000 PRESCRIPTIONS A DAY. DESPITE THESE CONCERNS, THE MPA, THE MCPS, AND MANITOBA'S INTERNET PHARMACIES RECENTLY SIGNED OFF ON A GOM PLAN TO ELIMINATE CO-SIGNING BY A CANADIAN PHYSICIAN ALTOGETHER AND TO ACCEPT PRESCRIPTIONS FROM U.S. PHYSICIANS ON PAR WITH THOSE FROM CANADA. THE GOM IS EXPECTED TO ANNOUNCE THEIR PROPOSAL SHORTLY AND SEEK THE NECESSARY LEGISLATIVE CHANGES TO DO AWAY WITH CO-SIGNING IN THE FALL. THE FEDERAL GOVERNMENT WILL LIKELY CHALLENGE THIS PROVINCIAL LEGISLATION.

¶6. THE STRONG PROMOTION OF THE INDUSTRY FROM MANITOBA OFFICIALS IS IN STARK CONTRAST TO THE CAUTIOUS APPROACH OF OTHER PROVINCIAL GOVERNMENTS AND REGULATORS. ONTARIO HAS TAKEN THE STRONGEST STANCE AGAINST INTERNET PHARMACIES, QUESTIONING BOTH THE LEGITIMACY OF THE CROSS-BORDER TRADE IN PRESCRIPTION PHARMACEUTICALS AND THE ABILITY OF THE PROVINCIAL REGULATORS TO EFFECTIVELY MONITOR THE SALE OF PRESCRIPTION DRUGS SOUTH OF THE BORDER. THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO, THE SELF-REGULATING BODY FOR THE PROVINCE'S MEDICAL PROFESSION, HAS STATED THAT "IT IS NOT ACCEPTABLE FOR A PHYSICIAN TO SIGN OR CO-SIGN A PRESCRIPTION WITHOUT ATTENDING THE PATIENT." THE ONTARIO COLLEGE OF PHARMACISTS HAS ALSO WEIGHED IN STATING THAT PHARMACISTS "SHALL NOT FACILITATE OR ENTER INTO AGREEMENTS WITH PHYSICIANS FOR THE PURPOSES OF CO-SIGNING OR REWRITING PRESCRIPTIONS FOR OUT-OF-COUNTRY PATIENTS." IN JUNE THE ONTARIO COURTS WILL HEAR A CASE AGAINST A NUMBER OF INDIVIDUALS AND COMPANIES DOING BUSINESS WITH AN ONLINE PHARMACY, THE CANADIAN DRUG STORE INC., WHICH IS ACCUSED OF UNLAWFULLY OPERATING AN UNACCREDITED INTERNET PHARMACY AND FILLING PRESCRIPTIONS WRITTEN BY U.S. PHYSICIANS FOR U.S. PATIENTS.

--CLOUDS LOOMING OVER THE INDUSTRY--

¶7. DESPITE THE INDUSTRY'S RECENT GROWTH, THE ENORMOUS POTENTIAL FOR LOWER-PRICED PRESCRIPTION DRUGS IN THE U.S. MARKETPLACE, AND STRONG SUPPORT FROM GOVERNMENT AND REGULATORY OFFICIALS, THE LONG-TERM VIABILITY OF THE CROSS-BORDER INTERNET PHARMACEUTICAL TRADE IS TENUOUS. IN ADDITION TO A POSSIBLE CRACKDOWN ON IMPORTERS BY THE FDA OR A LEGISLATIVE FIX BY CONGRESS TO PROVIDE SENIORS WITH PRESCRIPTION DRUG COVERAGE, THERE ARE SEVERAL DOMESTIC FACTORS THAT COULD SEVERELY DAMAGE THE CANADIAN INDUSTRY.

¶8. BRITISH PHARMACEUTICAL MANUFACTURER GLAXOSMITHKLINE (GSK), WHICH ANNOUNCED IN JANUARY THAT THEY WOULD NO LONGER SUPPLY THEIR PRODUCTS TO CANADIAN PHARMACIES SELLING TO THE U.S. MARKET, IS APPLYING THE GREATEST PRESSURE. PHARMACEUTICAL MANUFACTURES ARE CONCERNED THAT THE GROWING CROSS-BORDER TRADE COULD LEAD TO A NUMBER OF PROBLEMS: SHORTAGES OF BOTH CANADIAN PHARMACISTS AND DRUG PRODUCTS FOR CANADIAN CONSUMERS, DRUGS UNAPPROVED IN THE U.S. BEING DISPENSED TO U.S. PATIENTS, INFRINGEMENT OF U.S. PATENTS, AND POTENTIAL LIABILITY FOR CANADIAN DRUG COMPANIES. IN PRIVATE WE HAVE ALSO BEEN TOLD THAT FOR THE FIRST TIME COMPANIES HAVE EXPERIENCED DECREASED SALES OF KEY DRUGS IN NORTHERN BORDER STATES.

¶9. KRIS THORKELSON FROM CANADA DRUGS ADMITTED THAT SUPPLIES OF SOME GSK DRUGS ARE STARTING TO RUN SHORT. THE COMPANY HAS BEEN ABLE TO SECURE SUPPLIES THROUGH OTHER CANADIAN PHARMACIES, BUT IS BEGINNING TO EXPERIENCE DELAYS AND IS CONCERNED THAT THEY MAY NO LONGER BE ABLE MEET THE DEMAND. EFFORTS BY THE PHARMACEUTICAL EXPORTERS TO COUNTER GSK'S ACTIONS WERE DERAILED WHEN CANADA'S FEDERAL COMPETITION BUREAU RULED IN MARCH THAT GSK HAD A "REASONABLE BUSINESS JUSTIFICATION" TO BLOCK THE EXPORTS. ASTRAZENECA'S RECENT ANNOUNCEMENT THAT THEY WILL LIMIT SUPPLIES OF THEIR PRODUCTS TO CANADIAN PHARMACIES AND WHOLESALERS HAS COMPOUNDED THE SUPPLY PROBLEMS FOR INTERNET PHARMACIES.

¶10. A RELATED, AND YET UNTESTED, QUESTION IS HOW FEDERAL AND PROVINCIAL GOVERNMENTS WILL REACT IF THE DEMAND FROM INTERNET PHARMACIES BEGINS TO AFFECT THE SUPPLY OF DRUGS TO TRADITIONAL PHARMACIES SERVING CANADIAN PATIENTS. THE GOM IS PROMOTING A "MANITOBA FIRST" POLICY TO ENSURE THAT MANITOBA PATIENTS ARE NOT DENIED ACCESS TO DRUGS IF THERE IS A SHORTAGE, BUT THE POLICY LACKS THE REGULATORY TEETH THAT WOULD FORCE PHARMACIES TO SELL TO THE MANITOBA MARKET. FEDERAL REGULATIONS DO NOT STIPULATE THAT PHARMACIES MUST MAINTAIN AN ADEQUATE SUPPLY OF DRUGS OR COMPEL THEM TO GIVE FIRST PRIORITY TO CANADIAN CONSUMERS. BOTH HEALTH CANADA AND INDUSTRY CANADA ARE MONITORING THE CANADIAN DRUG SUPPLY AND HAVE INDICATED THAT THEY WOULD INTERVENE IN EMERGENCY CIRCUMSTANCES, AS THEY DID WHEN THERE WAS A

RUN ON CIPRO DURING THE ANTHRAX SCARE IN 2001.

¶11. PROVINCIAL EFFORTS TO PROMOTE THE PHARMACEUTICAL EXPORT INDUSTRY ARE ALSO BEING CLOSELY WATCHED BY THE FEDERAL GOVERNMENT. PROVINCIAL REGULATORS SET AND ENFORCE THE PROFESSIONAL STANDARDS FOR PHYSICIANS AND PHARMACISTS, BUT HEALTH CANADA, THROUGH THE HEALTH ACT AND FOOD AND DRUG ACT, IS ULTIMATELY RESPONSIBLE FOR THE SAFETY OF FOODS, DRUGS AND HEALTH PRODUCTS. IN A RECENT MEETING WITH USG OFFICIALS, DAVID EDWARDS, LEGAL COUNSEL AT HEALTH CANADA, NOTED THAT ACCORDING TO THE HEALTH ACT, A "PRACTITIONER" MUST BE A CANADIAN, AND THAT IT WOULD NOT BE POSSIBLE FOR THE GOM TO ELIMINATE THE NEED FOR A CANADIAN DOCTOR TO CO-SIGN A PRESCRIPTION BEFORE IT COULD BE FILLED BY A CANADIAN PHARMACIST.

--COMMENT--

¶12. DEPENDING ON WHOM ONE SPEAKS WITH AND THEIR RELATION TO THE PHARMACEUTICAL INDUSTRY, BI-NATIONAL TRADE IN PRESCRIPTION PHARMACEUTICALS IS EITHER A MARKET WITH HUGE GROWTH POTENTIAL FOR RURAL CANADIAN COMMUNITIES, OR A LEGALLY QUESTIONABLE BUSINESS THAT HAS ACHIEVED TEMPORAL SUCCESS ARBITRAGING GAPS IN REGULATIONS AND PRICES. THE LEGAL FRAMEWORK SURROUNDING THE CROSS-BORDER TRADE HAS NOT BEEN SOLIDIFIED ON EITHER SIDE OF THE BORDER, AND UNTIL IT IS MANY OF THE ISSUES WILL REMAIN OPEN TO INTERPRETATION. OTHER PROVINCES ARE PAYING CLOSE ATTENTION TO DEVELOPMENTS IN MANITOBA TO SEE HOW THE INTERNET BUSINESS MODEL WILL RESPOND TO CHANGES IN THE MARKETPLACE AND WHAT IMPACTS THIS MAY HAVE FOR THE CANADIAN HEALTH CARE SYSTEM.

CELLUCCI#